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PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE, SUITE 1200
1201 PEACHTREE STREET
ATLANTA, GA 30361

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JIANG, SHAOJIA A	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/086,398
Filing Date: February 28, 2002
Appellant(s): YANKNER ET AL.

Rivka D. Monheit
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 23, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments filed before Final on September 11, 2003 contained in the brief is correct.

However, the amendment after final rejection filed on May 2, 2004 has not been entered.

(5) Summary of claimed subject matter

The summary of invention contained in the brief is correct.

(6) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(7) Prior Art of Record

4,866,090	Hoffman et al.	09-1989
5,350,758	Wannamaker et al.	09-1994
5,362,732	Spielvogel et al.	11-1994

(6) Grounds of Rejection to be Reviewed on Appeal.

Note that this application is a divisional of Serial No. 09239387 now patented 6,440,387, which is a divisional of Serial No. 09046235 filed March 23, 1998, now patented 6,080,778. Thus, the effective filing date of the instant application is March 23, 1998.

Thus, the rejections made under 35 U.S.C. 102(**a**) set forth in the prior Office Action mailed February 24, 2004 were intended to be made under 35 U.S.C. 102(**b**) since all prior art of record was patented in this country, more than one year prior to March 23, 1998, the date of application for patent in the United States. The typographic error or oversight for this is regretted.

Moreover, the rejections made under 35 U.S.C. 102 set forth in the prior Office Action mailed February 24, 2004, will be presented and addressed separately below as the examiner intended originally, i.e., each 102(b) rejection anticipated by one reference.

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al. (4,866,090). This rejection is set forth in the prior Office Action mailed February 24, 2004 and reiterated below.

Hoffman et al. teach at column 1, lines 5-65, column 2 line 50 to column 8 line 39 and column 9 lines 50-62 lovastatin, pravastatin and simvastatin of claim 24 and that each of these compounds inhibit cholesterol by inhibiting (claims 26 and 27) the enzyme, HMG CoA reductase as claimed in claim 24 and inherently decreasing the production of Aβ to decrease blood levels as recited in claim 23. It is to be understood that these claimed known compounds as claimed by applicants are well known anti-cholesterol agents.

Thus, the disclosure of Hoffman et al. anticipates claims 23-27.

Claims 23 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Wannamaker et al. (5,350,758). This rejection is set forth in the prior Office Action mailed February 24, 2004 and reiterated below.

Wannamaker et al. disclose and teach at column 2 lines 12-17 and column 2 line 20 to column 3 line 16 that the compounds taught therein have activity of inhibiting squalene epoxidase and/or 2,3-oxidosqualene cyclase to inhibit cholesterol as claimed in applicants' claims 27 and 28. The pharmaceutical compositions of the claimed biological pathway are taught at column 14 line 66 to column 14 line 44.

Thus, the disclosure of Wannamaker et al. anticipates claims 23 and 27-28.

Claims 23 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Spielvogel et al. (5,362,732). This rejection is set forth in the prior Office Action mailed February 24, 2004 and reiterated below.

Spielvogel et al. disclose at column 8, lines 33-42 (see lines 38-42) that a pharmaceutical composition of claim 29 comprising nicotinic acid or probucol is known to be used in treating hyperlipidemic patients.

Thus, the disclosure of Spielvogel et al. anticipates claims 23 and 29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wannamaker et al. (5,350,758). This rejection is set forth in the prior Office Action mailed February 24, 2004 and reiterated below.

As stated above Wannamaker et al. teach the pharmaceutical formulation of compounds which inhibit 2,3-oxidosqualene cyclase to inhibit cholesterol as claimed by applicants' claim 26 -28.

The difference between the reference and applicants' claim 26 is that the reference fails to teach the uptake of dietary cholesterol. However, one skilled in the ad

would be motivated to use the compounds claimed in Wannamaker et al. to cause the uptake of dietary cholesterol since the reference teaches at column 16, lines 44-64 that the compounds can be within an oral form with an edible carrier.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness is presented.

(11) Response to Argument

Claim Rejections -35 USC § 102 Maintained

It is the examiner's position that the present invention is clearly anticipated by the prior art of record, as discussed below.

Appellants primarily argue that "[t]he claims on appeal define a composition comprising an effective amount of a compound decreasing blood cholesterol levels **to decrease Aβ production by neuronal cells in an individual at risk of developing Alzheimer's**. There is no teaching or suggestion in the prior art that the compounds disclosed have any effect on the production of Aβ protein in neuronal cells. The prior art fails to define this end point or what an effective dosage would be to achieve this endpoint" (emphasis original, see Appellants' brief, page 7). Appellants further argue that "the dosages that are effective in lowering the amount of amyloid precursor protein to decrease production of Aβ are different from those versus lowering cholesterol to treat or prevent atherosclerosis are different". Appellants also assert that "a 10%

decrease in serum cholesterol levels is believed to be sufficient to decrease production of Aβ protein in neurons" as taught in the specification.

Appellants' arguments herein are not found persuasive. First, as noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example. In this case, the claims are not limited to 10% decrease in serum cholesterol levels.

Second, given their broadest reasonable interpretation during patent examination, the claims herein read on a composition comprising any effective amounts of a compound that decrease blood cholesterol at any levels. Note that "to decrease Aβ production by neuronal cells in an individual at risk of developing Alzheimer's" merely states the inherent result of the limitation which is a compound that decrease blood cholesterol levels. Thus, the effective amounts for decrease blood cholesterol are deemed to overlap with the amounts to decrease Aβ production by neuronal cells in an individual at risk of developing Alzheimer's. Therefore, the cited prior art would inherently meet the claim limitations as discussed in the rejection above.

Moreover, Hoffman et al. (4,866,090) discloses that the effective amounts or doses of the statin in claim 25, the HMG CoA reduccase inhibitor, for treating hypercholesterol patients are about 10-2000 mg/day, preferably 10-100 mg/day.

The examiner also notes that Scolnick (WO 95/06470, PTO-892) discloses that the effective amounts of HMG-CoA reductase inhibitors such as lovastatin, simvastatin, pravastatin, and fluvastatin which are known to decrease blood cholesterol levels and used therein for treating and preventing the onset of Alzheimer's disease, are about 1-1000 mg/day, preferably 5-100 mg/day (see page 11 line 13-14).

Thus, the effective amounts for decreasing blood cholesterol are known to overlap with the amounts to decrease Aβ production by neuronal cells in an individual at risk of developing Alzheimer's.

Note that the Scolnick mentioned herein is not cited or added as prior art for any rejections herein but for its teaching that clearly supports the examiner's position based on inherency regarding the same or overlapping effective amounts of the compounds herein.

Therefore, the disclosure of the cited prior art clearly anticipates the claimed invention herein.

Furthermore, note that the instant specification fails to disclose any specific amounts or any dosage range of any statin in claim 25 (an HMG CoA reduccase inhibitor) or any inhibitors in claim 28-29 to achieve the end point herein, decreasing blood cholesterol at any levels "to decrease Aβ production by neuronal cells in an individual at risk of developing Alzheimer's".

Claim Rejection of Claims 26-27 under 35 USC § 103 over Wannamaker et al.

Maintained

Again Appellants argue that [t]here is no teaching or suggestion that the compound disclosed would have any effect on the production of Aβ in neuronal cells.

Appellants' argument herein are not found persuasive. Claims 26-27 merely recite the mechanism of action or the inherently property of the compound herein.

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Thus, this 103 rejection is based on inherency. Court has sanctioned practice of nominally basing rejection on 35 U.S.C. 103 when, in fact, actual ground of rejection is that claims are anticipated by prior art; justification for sanction is that lack of novelty is epitome of obviousness. *In re Pearson*, 181 USPQ 641.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

S. A. Jiang, Ph.D.
Primary Examiner
February 3, 2005

Conferees

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER